K083059

October 9, 2008

JAN 30 2009

Section III – 510(k)

Summary of Safety and Effectiveness

FDA CDRH DMC

JAN 27 2009

Received

K-37

Submitter:

DPM USA Corp.
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Miami, Florida 33172
Phone: 305-640-9894
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Contact Person: George Echeverri

Summary Prepared Date: October 9, 2008

Device Name:

I. Trade Name- Air Sonic Scaler
II. Common Name- Air-Powered Ultrasonic Scaler
III. Classification Name- Ultrasonic Scaler
IV. Classification Number: 21 CFR 872.4850
V. Product Code: ELC

Device for Which Substantial Equivalence is Claims:

1. Lynx-SM, Scaler Dental Handpiece
2. 510 (k) K901488
3. Manufacture: MTI Precision Products, Inc.

Device Description / Intended Use:

The Air Sonic Scaler, is intended for use by medical professionals during cleaning and periodontal therapy to remove calculus and tartar deposits and stains from teeth using the application of an ultrasonically vibrating frequency through a surgical 440A stainless steel tip. The tip comes in 3 different shapes (AS1, AS2, AS3) and is designed to generate a vibrating frequency of 6,000 Hz.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2009

Mr. George Echeverri
Director
DPM USA Corporation
1460 NW 107 Avenue, Suite G
Miami, Florida 33172

Re: K083059
Trade/Device Name: Air Sonic Scaler
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: October 9, 2008
Received: January 27, 2009

Dear Mr. Echeverri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if know):

Device Name: Air Sonic Scaler

Indications for Use:

The intended use of the Air Sonic Scaler is intended for use by dental professionals during dental cleaning and periodontal therapy to remove calculus and tartar deposits from teeth.

Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K053059